

SOLICITOR

AO 120 (Rev. 3/04)

SEP 10 2007

<p>TO: Mail Stop 8 Director of the U.S. Patent and Trademark Office P.O. Box 1450 Alexandria, VA 22313-1450</p>	<p>REPORT ON THE FILING OR DETERMINATION OF AN ACTION REGARDING A PATENT OR TRADEMARK</p>
--	--

In Compliance with 35 U.S.C. § 290 and/or 15 U.S.C. § 1116 you are hereby advised that a court action has been
filed in the U.S. District Court TRENTON on the following ☒ Patents or ☐ Trademarks:

DOCKET NO. 07-4213(JAP)	DATE FILED 9/5/2007	U.S. DISTRICT COURT TRENTON
PLAINTIFF SEPRACOR INC. and UNIVERSITY OF MASSACHUSETTS		DEFENDANT SUN PHARMACEUTICAL INDUSTRIES LTD
PATENT OR TRADEMARK NO.	DATE OF PATENT OR TRADEMARK	HOLDER OF PATENT OR TRADEMARK
1 7,211,582		SEE ATTACHED COMPLAINT
2 7,214,683		
3 7,214,684		
4		
5		

In the above—entitled case, the following patent(s)/ trademark(s) have been included:

DATE INCLUDED	INCLUDED BY <input type="checkbox"/> Amendment <input type="checkbox"/> Answer <input type="checkbox"/> Cross Bill <input type="checkbox"/> Other Pleading
PATENT OR TRADEMARK NO.	DATE OF PATENT OR TRADEMARK
1	
2	
3	
4	
5	

In the above—entitled case, the following decision has been rendered or judgement issued:

DECISION/JUDGEMENT

CLERK WILLIAM T. WALSH, CLERK	(BY) DEPUTY CLERK <i>[Signature]</i>	DATE 9/5/2007
---	---	------------------

Copy 1—Upon initiation of action, mail this copy to Director Copy 3—Upon termination of action, mail this copy to Director
Copy 2—Upon filing document adding patent(s), mail this copy to Director Copy 4—Case file copy

using, importing, offering to sell, or selling Sun's Proposed Products until after the expiration of the '683 patent, including any regulatory or patent term extension;

I. Preliminary and permanent injunctions enjoining Sun and its officers, agents, attorneys and employees, and those acting in privity or concert with it, from making, using, importing, offering to sell, or selling Sun's Proposed Products until after the expiration of the '684 patent, including any regulatory or patent term extension;

J. A declaration that the commercial manufacture, use, importation into the United States, sale or offering for sale of Sun's Proposed Products will directly infringe or induce and/or contribute to infringement of the '582 patent;

K. A declaration that the commercial manufacture, use, importation into the United States, sale or offering for sale of Sun's Proposed Products will directly infringe or induce and/or contribute to infringement of the '683 patent;

L. A declaration that the commercial manufacture, use, importation into the United States, sale or offering for sale of Sun's Proposed Products will directly infringe or induce and/or contribute to infringement of the '684 patent;

M. If Sun engages in the commercial manufacture, use, importation into the United States, offer to sell, or sale of Sun's Proposed Products prior to the expiration of the '582 patent, a judgment awarding damages to Plaintiffs resulting from such infringement, increased to treble the amount found or assessed based on the willfulness of the infringement, together with interest;

N. If Sun engages in the commercial manufacture, use, importation into the United States, offer to sell, or sale of Sun's Proposed Products prior to the expiration of the '683 patent, a judgment awarding damages to Plaintiffs resulting from such infringement, increased to

treble the amount found or assessed based on the willfulness of the infringement, together with interest;

O. If Sun engages in the commercial manufacture, use, importation into the United States, offer to sell, or sale of Sun's Proposed Products prior to the expiration of the '684 patent, a judgment awarding damages to Plaintiffs resulting from such infringement, increased to treble the amount found or assessed based on the willfulness of the infringement, together with interest;

P. Attorneys' fees in this action based on willful infringement pursuant to 35 U.S.C. § 284 and/or as an exceptional case pursuant to 35 U.S.C. § 285 and 271(e)(4);

Q. Costs and expenses in this action; and

R. Such further and other relief as this Court may deem just and proper.

Dated: September 4, 2007

Respectfully submitted,

s/ Charles M. Lizza

Charles M. Lizza
William C. Baton
Saul Ewing LLP
One Riverfront Plaza
Newark, New Jersey 07102-5490
(973) 286-6700
clizza@saulewing.com

*Attorneys for Plaintiffs
Sepracor Inc. and
University of Massachusetts*

OF COUNSEL:

Lester J. Savit
Jordan A. Gimbel
JONES DAY
3 Park Plaza
Suite 1100
Irvine, California 92614
(949) 851-3939
ljsavit@jonesday

LOCAL CIVIL RULE 11.2 CERTIFICATION

I hereby certify that the matters captioned: (1) *Schering Corporation v. Zydus Pharmaceuticals, USA, Inc., et al.*, Civil Action No. 06-4715 (D.N.J.); (2) *Schering Corporation v. Caraco Pharmaceutical Laboratories Ltd., et al.*, Civil Action No. 06-14386 (E.D. Mich.); and (3) *Schering Corporation v. GeoPharma Inc., et al.*, Civil Action No. 06-1843 (M.D. Fla.), which have been consolidated before the Honorable Mary L. Cooper under the caption, *In Re: Desloratadine Patent Litigation*, MDL No. 1851 (D.N.J.)(MLC), are related patent infringement cases because the defendant in the matter in controversy is a defendant in the previously identified consolidated matter, and the alleged acts of infringement are the same, *e.g.*, based upon the defendant's filing of the same ANDA. Also, the patents asserted in the current matter are related to the previously identified matters because all the patents are associated with Clarinex® products.

I also certify that the matter captioned, *Sepracor Inc. et al., v. Glenmark Pharmaceuticals, Ltd., et al.* Civil Action No. 07-3385 (D.N.J.)(SRC), is related because it involves the same plaintiffs and two of the same patents as the matter in controversy.

I further certify that, to the best of my knowledge, the matter in controversy is not the subject of any other action pending in any court, or of any pending arbitration or administrative proceeding.

Dated: September 4, 2007

By: s/ Charles M. Lizza
Charles M. Lizza
William C. Baton
Saul Ewing LLP
One Riverfront Plaza
Newark, New Jersey 07102-5490
(973) 286-6700
clizza@saul.com

*Attorneys for Plaintiffs
Sepracor Inc. and
University of Massachusetts*

OF COUNSEL:

Lester J. Savit

Jordan A. Gimbel

JONES DAY

3 Park Plaza

Suite 1100

Irvine, California 92614

(949) 851-3939

ljsavit@jonesday.com

Charles M. Lizza
William C. Baton
Saul Ewing LLP
One Riverfront Plaza
Newark, New Jersey 07102-5490
(973) 286-6700
clizza@saul.com

*Attorneys for Plaintiffs
Sepracor Inc. and
University of Massachusetts*

UNITED STATES DISTRICT COURT
DISTRICT OF NEW JERSEY

SEPRACOR INC. and UNIVERSITY
OF MASSACHUSETTS,

Plaintiffs,

v.

SUN PHARMACEUTICAL
INDUSTRIES LTD.

Defendant.

Civil Action No.:

07-4213 (JAP)

COMPLAINT FOR PATENT
INFRINGEMENT

(Filed Electronically)

Plaintiffs Sepracor Inc. ("Sepracor") and University of Massachusetts ("UMass"),
by their attorneys, for their Complaint against Defendant Sun Pharmaceutical Industries Ltd.
("Sun") hereby allege as follows:

Nature of the Action

1. This is an action for patent infringement arising under the patent laws of the United States, 35 U.S.C. § 100 *et seq.*, arising from Defendant's filing of an Abbreviated New Drug Application ("ANDA") with the United States Food and Drug Administration ("FDA") seeking approval to commercially market a generic version of the patented Clarinex® drug products prior to the expiration of the United States Patent Nos. 7,211,582 ("the '582

patent”), 7,214,683 (“the ‘683 patent”) and 7,214,684 (“the ‘684 patent”), which are owned by Sepracor and UMass.

The Parties

2. Plaintiff Sepracor is a corporation organized and existing under the laws of the State of Delaware, having a place of business at 84 Waterford Drive, Marlborough, Massachusetts 01752.

3. Plaintiff UMass is a public institution of higher education of the Commonwealth of Massachusetts, having a place of business at 55 Lake Avenue North, Worcester, Massachusetts 01655.

4. Upon information and belief, Sun is a corporation organized and existing under the laws of India, having a place of business at Acme Plaza, Andheri Kurla Road, Andheri (East), Mumbai 400 059, India. Upon information and belief, Sun, through its wholly-owned subsidiary, Sun Pharmaceutical Industries Inc. (“Sun NJ”), leases a manufacturing facility at 270 Prospect Plains Road, Cranbury, NJ 08512, owns a facility at 6 Hollywood Court, South Plainfield, New Jersey 07080 and owns a manufacturing facility located at 1 Able Drive, Cranbury, NJ 08512. Sun NJ maintains a registered agent, Corporation Service Company, at 830 Bear Tavern Road, West Trenton, New Jersey 08628.

5. Upon information and belief, Sun conducts business through and with its subsidiary, Sun NJ, which maintains a manufacturing facility at 1 Able Drive, Cranbury, NJ 08512.

6. Upon information and belief, Sun is in the business of manufacturing generic pharmaceutical products, which are copies of products invented and developed by innovator pharmaceutical companies.

7. Upon information and belief, Sun assembled and caused to be filed with the United States Food and Drug Administration ("FDA"), pursuant to 21 U.S.C. § 355(j), ANDA No. 78-359 concerning generic versions of tablets containing 5 milligrams of Clarinex[®] brand desloratadine per tablet ("Sun's Proposed Product").

8. Upon information and belief, if ANDA No. 78-359 is approved, it is the intention of Sun to distribute Sun's Proposed Product in the United States.

Jurisdiction and Venue

9. This Court has jurisdiction over the subject matter of this action pursuant to 28 U.S.C. §§ 1331 and 1338(a).

10. This court has personal jurisdiction over Sun. Upon information and belief, Sun is in the business of manufacturing, marketing, importing and selling pharmaceutical drug products, including generic drug products. Upon information and belief, Sun directly, or through its subsidiaries, agents and/or alter-egos (including Sun NJ), manufactures, markets and sells generic drugs throughout the United States and in this judicial district. Upon information and belief, Sun purposefully has conducted and continues to conduct business, directly, and/or through its subsidiaries, agents and/or alter-egos (including Sun NJ) in this judicial district, and this judicial district is a likely destination of Sun's ANDA Product. Upon information and belief, Sun, through its subsidiaries, agents, and/or alter-egos (including Sun NJ) leases and owns facilities in this judicial district and retains a registered agent in this judicial district. Upon information and belief, Sun has previously submitted to the jurisdiction of this Court and has further previously availed itself of this Court by filing suit in this jurisdiction and by asserting counterclaims in other civil actions initiated in this jurisdiction. For example, Sun consented to jurisdiction in *Otsuka Pharmaceutical Co., Ltd. v. Sun Pharmaceutical Industries Ltd.*, 07-cv-01516 and *PDL BioPharma, Inc. v. Sun Pharmaceutical Industries Ltd.*, 07-cv-01788; Sun

admitted jurisdiction is proper in New Jersey in *Altana Pharma AG v. Sun Pharmaceutical Industries Ltd.*, 05-cv-3920; Sun participated in the New Jersey bankruptcy case, *Able Laboratories, Inc. and Estate of the Post-Confirmation Debtor*, 05-33129; and Sun filed a lawsuit against Altana Pharma AG in New Jersey, *Sun Pharmaceutical Industries Ltd. v. Altana Pharma AG et al.*, 05-cv-2391.

11. Venue is proper in this judicial district pursuant to 28 U.S.C. §§ 1391 and 1400(b).

The Patents In Suit and the Clarinex[®] Drug Products

12. On May 1, 2007, the '582 patent, entitled "Methods for Treating Urticaria Using Descarboethoxyloratadine," was duly and legally issued. Sepracor and UMass are assignees of the entire right, title and interest in the '582 patent. A copy of the '582 patent is attached hereto as Exhibit A.

13. On May 8, 2007, the '683 patent, entitled "Compositions of Descarboethoxyloratadine," was duly and legally issued. Sepracor and UMass are assignees of the entire right, title and interest in the '683 patent. A copy of the '683 patent is attached hereto as Exhibit B.

14. On May 8, 2007, the '684 patent, entitled "Methods for the Treatment of Allergic Rhinitis," was duly and legally issued. Sepracor and UMass are assignees of the entire right, title and interest in the '684 patent. A copy of the '684 patent is attached hereto as Exhibit C.

15. The '582, '683 and '684 patents are identified in the FDA publication entitled "Approved Drug Products with Therapeutic Equivalence Evaluations" in association with 5 milligram desloratadine tablets, which are sold as a commercial product under the trade

name Clarinex[®]. These patents cover approved uses of commercial Clarinex[®] and approved Clarinex[®] products.

Acts Giving Rise to this Action

16. Plaintiffs Sepracor and UMass received a letter from Sun, dated July 23, 2007 ("the Notification Letter"), notifying them that Defendant had filed with the FDA an ANDA (No. 78-359) under § 505(j) of the Federal Food, Drug, and Cosmetic Act (21 U.S.C. § 355(j)) to obtain FDA approval to engage in the commercial manufacture, importation, use, offer for sale or sale of generic tablets containing 5 milligrams of Clarinex[®] brand desloratadine per tablet.

17. Upon information and belief, Sun intends to engage and will engage in the commercial manufacture, importation, use, offer for sale or sale of Sun's Proposed Products promptly upon receiving FDA approval to do so.

18. The Notification Letter states that ANDA No. 78-359 contains a "Paragraph IV Certification" that, in Sun's opinion, the '582, '683 and '684 patents are invalid, unenforceable and/or not infringed.

19. The Notification Letter does not allege any basis for an allegation that the '582, '683 and '684 patents will not be infringed by the commercial manufacture, importation, use, offer for sale or sale of Sun's Proposed Products other than alleged invalidity.

20. Upon information and belief, ANDA No. 78-359 contains information showing that Sun's Proposed Products (a) are bioequivalent to a patented Clarinex[®] 5 milligram tablet product; (b) have the same active ingredient as a patented Clarinex[®] 5 milligram tablet product; (c) have the same route of administration and strength as a patented Clarinex[®] 5 milligram tablet product; and (d) have the same, or substantially the same, proposed labeling, and the same indication and usage as a patented Clarinex[®] 5 milligram tablet product.

21. This action is being brought pursuant to 21 U.S.C. § 355(j)(5)(B)(iii) before the expiration of forty-five days from the date of receipt of the Notification Letter.

Count I – Infringement of the ‘582 Patent by Defendant

22. Plaintiffs repeat and reallege the allegations of paragraphs 1-21 as though fully set forth herein.

23. Sun’s submission of an ANDA including its § 505(j)(2)(A)(vii)(IV) certification to obtain approval to engage in the commercial manufacture, importation, use, offer for sale or sale of Sun’s Proposed Products, prior to the expiration of the ‘582 patent, constitutes infringement of one or more of the claims of the ‘582 patent under 35 U.S.C. § 271(e)(2)(A).

24. Unless enjoined by this Court, Sun, upon FDA approval of ANDA No. 78-359, will infringe the ‘582 patent under 35 U.S.C. § 271 by making, using, importing, offering to sell, or selling Sun’s Proposed Products in the United States.

25. Sun had notice of the ‘582 patent prior to undertaking its acts of infringement. Sun’s infringement of the ‘582 patent has been, and continues to be, willful and deliberate.

26. Plaintiffs will be substantially harmed if Sun’s infringement of the ‘582 patent is not enjoined, and Plaintiffs are entitled to equitable relief.

Count II – Infringement of the ‘683 Patent by Defendant

27. Plaintiffs repeat and reallege the allegations of paragraphs 1-26 as though fully set forth herein.

28. Sun’s submission of an ANDA including its § 505(j)(2)(A)(vii)(IV) certification to obtain approval to engage in the commercial manufacture, importation, use, offer for sale or sale of Sun’s Proposed Products, prior to the expiration of the ‘683 patent, constitutes infringement of one or more of the claims of the ‘683 patent under 35 U.S.C. § 271(e)(2)(A).

29. Unless enjoined by this Court, Sun, upon FDA approval of ANDA No. 78-359, will infringe the '683 patent under 35 U.S.C. § 271 by making, using, importing, offering to sell, or selling Sun's Proposed Products in the United States.

30. Sun had notice of the '683 patent prior to undertaking its acts of infringement. Sun's infringement of the '683 patent has been, and continues to be, willful and deliberate.

31. Plaintiffs will be substantially harmed if Sun's infringement of the '683 patent is not enjoined, and Plaintiffs are entitled to equitable relief.

Count III – Infringement of the '684 Patent by Defendant

32. Plaintiffs repeat and reallege the allegations of paragraphs 1-31 as though fully set forth herein.

33. Sun's submission of an ANDA including its § 505(j)(2)(A)(vii)(IV) certification to obtain approval to engage in the commercial manufacture, importation, use, offer for sale or sale of Sun's Proposed Products, prior to the expiration of the '684 patent, constitutes infringement of one or more of the claims of the '684 patent under 35 U.S.C. § 271(e)(2)(A).

34. Unless enjoined by this Court, Sun, upon FDA approval of ANDA No. 78-359, will infringe the '684 patent under 35 U.S.C. § 271 by making, using, importing, offering to sell, or selling Sun's Proposed Products in the United States.

35. Sun had notice of the '684 patent prior to undertaking its acts of infringement. Sun's infringement of the '684 patent has been, and continues to be, willful and deliberate.

36. Plaintiffs will be substantially harmed if Sun's infringement of the '684 patent is not enjoined, and Plaintiffs are entitled to equitable relief.

Prayer for Relief

WHEREFORE, Plaintiffs respectfully request the following relief:

- A. A judgment declaring that Sun has infringed one or more claims of the '582 patent;
- B. A judgment declaring that Sun has infringed one or more claims of the '683 patent;
- C. A judgment declaring that Sun has infringed one or more claims of the '684 patent;
- D. An Order that the effective date of any FDA approval of ANDA No. 78-359 be no earlier than the date on which the '582 patent expires, including any regulatory or patent term extension;
- E. An Order that the effective date of any FDA approval of ANDA No. 78-359 be no earlier than the date on which the '683 patent expires, including any regulatory or patent term extension;
- F. An Order that the effective date of any FDA approval of ANDA No. 78-359 be no earlier than the date on which the '684 patent expires, including any regulatory or patent term extension;
- G. Preliminary and permanent injunctions enjoining Sun and its officers, agents, attorneys and employees, and those acting in privity or concert with it, from making, using, importing, offering to sell, or selling Sun's Proposed Products until after the expiration of the '582 patent, including any regulatory or patent term extension;
- H. Preliminary and permanent injunctions enjoining Sun and its officers, agents, attorneys and employees, and those acting in privity or concert with it, from making,